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Attorney Docket No.: 3564/1010 PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of:	Sedivy et al.	Examiner: Misook, Y.
Serial No.:	09/654,281	Group: 1642
Filed:	September 1, 2000	
Entitled:	KINASE INHIBITORS AND METHODS OF USE IN SCREENING ASSAYS AND MODULATION OF CELL PROLIFERATION AND GROWTH	Conf. No.: 5838

CERTIFICATE OF MAILING UNDER 37 CFR §1.8a

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TRANSMITTAL LETTER

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1. Statement of Substance; and
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The Commissioner for Patents is hereby authorized to charge any additional fees or credit any overpayment in the total fees to Deposit Account No. 16-0085, Reference 3564/1010. A duplicate of this transmittal letter is enclosed for this purpose.

Respectfully submitted,

Date: September 15, 2003

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STATEMENT OF SUBSTANCE UNDER 37 C.F.R. § 1.133

Sir:

This paper is responsive to the Interview Summary mailed August 14, 2003, and includes a complete written statement as to the substance of the telephonic interview between Examiners Misook Yu and Anthony Caputa and the Applicants' representatives, Elizabeth Spar and Barbara A. Gyure on July 30, 2003. The Statement includes the reasons presented during the interview that warranted favorable action, in compliance with 37 C.F.R. § 1.133. A response to the outstanding final Office Action, also mailed August 14, 2003, will be mailed under separate cover.

During the above-referenced interview, the participants discussed the NINA mailed on May 19, 2003. Applicants' representatives described the differences between original claim 33 and claim 33 as amended, both of which are directed to the same patentable invention, as discussed in detail below. As a result of this discussion and as stated in the Interview Summary mailed August 14, 2003 (Paper No. 22), the participants agreed that the previous Amendment filed on January 17, 2003 (Paper No. 19) was fully responsive, and that the NINA would be

vacated and the claims as amended would be examined.

As an initial matter, the Applicants' representatives discussed MPEP § 2111 regarding claim interpretation, and the relevant case law, including *In re Hyatt*, 211 F.3d 1367, 54 USPQ2d 1664 (Fed. Cir. 2000); *In re Morris*, 127 F.3d 1048, 44 USPQ2d 1023 (Fed. Cir. 1997); and *In re Cortright*, 165 F.3d 1353, 49 USPQ2d 1464 (Fed. Cir. 1999). MPEP § 2111 states, and each of these cases confirm, that during examination the claims must be given their broadest reasonable interpretation consistent with the specification and as they would be understood by one of ordinary skill in the art.

Based on this precedent, Applicants' representatives argued that claim 33 as filed, which recites a method of inhibiting the activity of an RKIP-sensitive kinase using an agent which inhibits the activity of the kinase, should be broadly interpreted to include the use of an agent that increases or inhibits the activity of a polypeptide comprising an RKIP motif, as recited in amended claim 33. Specifically, original claim 33 states:

> A method of inhibiting the activity of an RKIP-sensitive kinase, comprising the step of contacting said RKIP-sensitive kinase with an amount of an agent which inhibits the activity of said RKIP-sensitive kinase sufficient to inhibit said activity.

Claim 33 as amended states:

> A method of inhibiting the phosphorylation activity of a signal transduction kinase that binds an RKIP family member, comprising the step of contacting said RKIP-sensitive kinase with an amount of an agent that increases or inhibits the activity of a polypeptide comprising an RKIP motif, wherein said agent inhibits the activity of said signal transduction kinase that binds an RKIP family member, sufficient to inhibit said activity.

In support of their position that the term "agent" broadly includes polypeptides with an RKIP motif, as well as other agents that modulate the activity of a polypeptide comprising an RKIP motif, the Applicants' representatives directed the Examiners' attention to specific

examples and passages in the specification. In particular, the Applicants' representatives noted the following:

(1) Exmple 2, which teaches inhibition of RKIP activity using antibodies.

(2) Example 3, which teaches inhibition of RKIP activity using antisense molecules.

(3) Page 15, line 13, through page 16, line 2, which defines the term "agent" as follows:

> "[t]he term "agent" means a composition that has the capacity to modify the bioactivity of a nucleic acid encoding or polypeptide comprising an RKIP motif so as to modulate the activity of a signal transduction pathway that is responsive to an RKIP family protein. An "agent" as used herein may either promote or inhibit the function of the signal transduction pathway, the expression of genes regulated by that pathway, or the ultimate outcome of that pathway's activation (e.g., proliferation, apoptosis, differentiation, etc.). Agents can include any recombinant, modified or natural nucleic acid molecule, library of recombinant, modified or natural nucleic acid molecules, synthetic, modified or natural peptide, library of synthetic, modified or natural peptides; organic or inorganic compound, or library of organic or inorganic compounds (including small molecules) where the agent has the capacity to modify the bioactivity of an RKIP motif-bearing polypeptide."

(4) The section on pages 60-66, entitled "Candidate Agents," which describes candidate agents and their properties, including nucleic acids (pages 62-66), such as antisense nucleic acids.

(5) Page 58, line 19, through page 59, line 3, which states that "[t]he phosphorylation of kinase targets may be monitored as a more direct assay for RKIP activity. Because RKIP family members inhibit kinase activity, monitoring the activity of these target kinases in the presence or absence of candidate RKIP modulators permits one to determine the effect of a candidate modulator on RKIP activity. A decrease in RKIP target kinase activity is indicative of increased RKIP activity, while an increase in

target kinase activity is indicative of decreased RKIP activity" (emphasis added).

(6) Page 73, lines 9-12, which states that "an agent that enhances RKIP kinase inhibiting activity may be monitored by monitoring RKIP-sensitive kinase activity in the tissue, while an agent that modulates RKIP expression may be monitored by following that expression."

Thus, Applicants' representatives argued that claim 33 as filed is not limited to a particular subset of agents that are polypeptides with an RKIP motif. Rather, the specification clearly teaches inhibition of the phosphorylation activity of a signal transduction kinase with an agent that increases or inhibits the activity of a polypeptide comprising an RKIP motif.

In view of all of the above, the "broadest reasonable interpretation", consistent with the specification of the invention as recited in original claim 33, clearly encompasses agents in addition to polypeptides having an RKIP motif, and in particular, agents that interact with a second protein having an RKIP motif. Amended claim 33 claims an invention that is not patentably distinct from the invention originally examined. Thus, Applicants' representatives argued that the response to the Office Action dated October 17, 2002 was responsive, and that the amendment to claim 33 should be entered.

As stated in the Interview Summary, agreement was reached during the interview; the NINA will be vacated and amended claim 33 will be examined in the next office action.

Respectfully submitted,

Date: Sep. 15, 2003

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